

Notice of Allowability

Application No.

09/914,651

Examiner

David Guzo

Applicant(s)

MOLLOY ET AL.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 9/6/05 and interview of 9/21/05.
2. ☒ The allowed claim(s) is/are 54-59,61-65,67,69-78,83-85,87-92,95,97-102 and 106-115.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 8/31/01
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 9/21/05.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Examiner's Amendment

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 9/21/05, Judith Toffenetti requested an extension of time for ONE MONTH(S) and authorized the Director to charge Deposit Account No. 500417 the required fee of \$570.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In the Claims:

56. (Currently amended) A recombinant polynucleotide according to claim 55~~54~~ in which the promoter is located upstream from and is operably linked to the sequence encoding the heterologous polypeptide.

58. (Currently amended) A recombinant polynucleotide according to claim 57~~54~~ in which the promoter active in the prostate is selected from the group consisting of a probasin promoter, a PSM promoter and a PSA promoter.

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73. (Previously presented) A recombinant expression cassette according claim 65 in which the expression cassette comprises a dimer or higher multimer comprising two or more enhancer elements ~~derived~~ obtained from intron 3 of the PSM gene.

Cancel Claims 79-82.

83. (Currently amended) A vector ~~according to claim 82 which further comprises~~ comprising a gene encoding a selectable marker and an isolated nucleic acid molecule, the nucleic acid molecule having enhancer activity and comprising:

(a) a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11,

or

(b) a nucleic acid sequence which hybridises under high stringency 0.1 x SSC and 0.1%(w/v) SDS at 50°C wash conditions to the sequence defined in paragraph (a).

84. (Currently amended) A vector according to claim ~~83~~82 in which the vector is a human adenovirus Type 5 or ovine adenovirus.

114. (New) A vector comprising a gene encoding a selectable marker and an isolated nucleic acid molecule, the nucleic acid molecule having enhancer activity and comprising:

(a) a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11,

or

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(b) a nucleic acid sequence which hybridises under high stringency 0.1 x SSC and 0.1%(w/v) SDS at 50°C wash conditions to the sequence defined in paragraph (a).

115. (New) A vector according to claim 114 in which the vector is a human adenovirus Type 5 or ovine adenovirus.

An examination of the prosecution history in the instant cases revealed that a reference (US Patent 5,538,866) cited on an Information Disclosure Statement filed 8/31/01 was not initialled or crossed through by the previous Examiner. A copy of the PTO-1449 with the reference initialled is provided with this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
September 21, 2005


DAVID GUZO
PRIMARY EXAMINER